A-1. Summary of Requirements for Primary PCI Programs: Hospitals with and without On-Site Cardiac Surgery

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Institutional Resources	1) All institutions should provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week.	**Yes**	**Yes**
	2) All institutions should provide primary PCI as soon as possible and not to exceed 120 minutes from patient arrival (i.e., door-to-balloon time of ≤ 120 minutes) for 80 percent of appropriate patients.	**Yes**	**Yes**
	3) All institutions should have adequate physician, nursing, and technical staff to provide cardiac catheterization laboratory and coronary care unit services to acute MI patients 24 hours per day, seven days per week.	**Yes**	**Yes**
	4) All institutions should have a written commitment by hospital administration signed by the hospital president to support the program, and be required to:	**Yes**	**Yes**
	i) identify a physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges;	**Yes**	**Yes**
	ii) develop a formal, regularly scheduled (meetings every other month) interventional case review that requires attendance by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients; and	**Yes**	**Yes**
	iii) create a multiple care area group (emergency department, coronary care unit, and cardiac catheterization laboratory) that includes at a minimum the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Institutional Resources (Continued)	5) All institutions should design and implement a formal continuing medical education program for staff, particularly in the cardiac catheterization laboratory and coronary care unit.	**Yes**	**Yes**
	6) There must be a formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, for hospitals performing primary PCI without on-site cardiac surgery.	**Not Applicable**	**Yes**
	7) There must be a formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by hospitals performing primary PCI without on-site cardiac surgery.	**Not Applicable**	**Yes**
Physician Resources	1) Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year.	**Yes**	**Yes**
	2) Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MIs during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.	**Yes**	**Yes**
	3) Physicians who perform primary PCI should agree to participate in an on-call schedule.	**Yes**	**Yes**
	4) Physicians who perform primary PCI should meet the credentialing criteria for the institution.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Initiation of New Primary PCI Program	1) The Maryland Health Care Commission should establish an application process to review requests submitted by hospitals seeking approval to provide primary PCI services without on-site cardiac surgery services.	**Not Applicable**	**Yes**
	2) All institutions should demonstrate that they have a minimum of 60-65 and optimally 85-90 acute ST-segment elevation MI's annually.	**Yes**	**Yes**
	3) Because primary PCI is a strategy of care involving a team of health care professionals in multiple care areas, all institutions should begin providing this service only after completing a development program that attends to setting of standards, training of staff, development of logistics and implementation of a formal quality and error management program. The application submitted to the Commission should describe in detail how the hospital proposes to undertake and complete a development program, which may include collaboration with an established primary PCI program. The development program should contain the following major components:		
	i) The standards contained in the American College of Cardiology/American Heart Association Guidelines for Management of Patients with Acute Myocardial Infarction and Guidelines for Percutaneous Coronary Intervention will be used to guide care provided in primary PCI programs.	**Yes**	**Yes**
	ii) Nursing and technical staff in both the catheterization laboratory and in pre and post-procedure care units will require additional training, including familiarization with angioplasty equipment, commonly used drugs, intra-aortic balloon counterpulsation equipment, patient transfer to and from the laboratory; and other pre-and post-procedure care issues.	**Yes**	**Yes**
	iii) The logistical issues that need to be addressed in the primary PCI development program include at a minimum: hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after primary angioplasty, plans for failed angioplasty, and fall-back plans for primary angioplasty system failure.	**Yes**	**Yes**
	iv) The quality and error management component of the primary angioplasty development program should give special emphasis to minimizing, discovering, reporting, and correcting error in the system of acute MI care.	**Yes**	**Yes**

Category	Recommended Requirement for Primary PCI Program	Hospitals with On-Site Cardiac Surgery	Hospitals without On-Site Cardiac Surgery
Patient Groups Suitable for Primary PCI in Settings without On-Site Cardiac Surgery	a) ST-segment elevation myocardial infarction (or new LBBB or ST-depression V1-V2 compatible with true posterior infarction) who are thrombolytic eligible or thrombolytic ineligible.	**Yes**	**Yes**
	b) When transfer to a tertiary institution may be harmful for patients with acute myocardial infarction in cardiogenic shock that the treating physician(s) believe, either because the patient is too unstable or because the temporal delay will result in worse outcomes.	**Not Applicable**	**Yes**
	c) Patients for whom the primary PCI system was not initially available, who received thrombolytic therapy that subsequently failed. These cases should constitute no more than 10 percent of all cases.	**Yes**	**Yes**
Minimum and Optimal Institutional Volume	All institutions should perform a minimum of 36 and optimally 49 primary PCI procedures annually. *(Note: A program performing at least 49 cases annually, or approximately one case per week, is more likely to have the logistics and staff available for timely reperfusion of acutely ill patients. If, however, rapid access to a program doing 49 cases is not available, then a site performing 36 or more cases/year is acceptable. This approach acknowledges important regional differences in access to primary PCI services. The lower volume standard should only be considered in areas of the state where access to a high volume program is not readily available.)*	**Yes**	**Yes**
Process and Outcome Measures for Ongoing Quality Assessment	Monitoring of the outcomes of care for patients presenting with ST-elevation MI will facilitate ongoing quality improvement efforts and provide the opportunity to measure program compliance, safety, and effectiveness. This requires that a uniform data set be developed, collected, and analyzed from all hospitals in Maryland offering primary PCI services. This data set should build upon the elements collected in the C-PORT project. Included would be data on: patient demographic and clinical characteristics; times of symptom onset, arrival in the emergency department, arrival in the catheterization lab, catheterization procedure onset and termination, balloon inflation, procedural outcome; complications; need for emergency cardiac surgery; incidence and indication for hospital transfers, adjunctive medical therapies and clinical outcomes (including in-hospital mortality and stroke and long-term follow-up).	**Yes**	**Yes**